REMARKS

This document is being filed in reply to the final Office Action mailed October 28, 2008 (the "Office Action"). Upon entry of this amendment, claims 1-3, 6, 8-10, 12, 22, 24, 31-34, 47, 50, 54-58, 61-74, 76-80 and 82-114 will be pending. Claims 1, 6, 8-10, 12, 22, 34, 54, 56-58, 65, 68-71, 82, 94-102, 105, 106 and 110 have been amended, claims 13, 14, 55, and 75 have been cancelled, and claims 111-114 have been newly added. Claims 4, 5, 7, 11, 15-21, 23, 25-30, 35-46, 48-49, 51-53, 59-60, and 81 were previously cancelled. Support for these amendments can be found throughout the specification as filed and is discussed in detail below. Support for new claims 111-114 can be found, e.g., in original claims 1, 13 and 14 and at page 20, line 26 to page 21, line 2. No new matter is added.

Withdrawn method claims 50, 54-58 and 82-94, directed to non-elected subject matter, are retained for possible rejoinder upon allowance of product claims.

The claim amendments made herein have been made solely to expedite prosecution of the present application and should not be construed as an acquiescence to any of the Office's rejections.

Amended independent claims 1 and 99 recite a compound (claim 1) or an isolated polypeptide (claim 99) containing a peptide or protein having sialidase activity, and a peptide or protein that binds to a glycosaminoglycan (GAG) on the surface of a target cell. Amended claims 1 and 99 also recite a sub-class of sialidase activities, *i.e.*, the sialidase activity is of a substrate specifity that cleaves α(2,3)-Gal and/or α(2,6)-Gal linkages. Support for these amendments can be found throughout the specification, for example, at page 8, line 27 to page 9, line 5; page 15, line 27 to page 16, line 2; page 20, line 26 to page 21, line 15; page 41, lines 14-24; page 42, line 11 to page 44, line 3; Example 2 beginning at page 35; Example 4 beginning at page 40; Example 5 beginning at page 46; Example 6 beginning at page 48; and Figures 3 and 4.

As the above cited sections describe, Applicants clearly contemplated and appreciated a wide variety of known viral, fungal, bacterial, human, *etc.* sialidases having α(2,3)-Gal and/or α(2,6)-Gal substrate specificity in the claimed compounds and polypeptides for the prevention

and treatment of infection by a pathogen. The cited sections extensively describe how sialidase peptides or proteins having α(2,3)-Gal and/or α(2,6)-Gal substrate specificity, when bound to target cells *via* a suitable glycosaminoglycan (GAG) – binding peptide or protein, can cleave sialic acid receptors on the target cell surface, thereby preventing and/or treating infection by pathogens whose mode of infection involves binding to sialic acid receptors. The cited sections further describe how the claimed compounds and polypeptides can be tailored in a narrow spectrum or broad spectrum fashion against one or more desired strains of viruses depending on the substrate specificity, namely, α(2,3)-Gal linkage, α(2,6)-Gal linkage or both (*see*, for example page 8, line 27 to page 9, line 5; page 15, line 27 to page 16, line 2; page 41, lines 14-24; page 42, line 11 to page 44, line 3 and Example 5 beginning at page 46, which describe how exemplary viral, bacterial or human sialidases with α(2,3)-Gal linkage specificity, α(2,6)-Gal linkage specificity or both may be selected depending on the pathogen at issue, *e.g.*, whether the virus is hosted in an avian, equine, porcine or human species). Applicants have also amended claims 34 and 94 to remove the recitation of "substantially homologous" sequences. Thus, Applicants clearly were in possession of the subject matter as claimed and the specification satisfies the written description requirement.

The sections and Examples cited above also teach how to make the claimed compounds and polypeptides that use known components (a peptide or protein having sialidase activity and a GAG-binding peptide or protein), how to measure their α(2,3)-Gal and/or α(2,6)-Gal sialidase activity using standard assays, and how to measure their effectiveness against pathogenic infection in standard tissue culture and animal models. Therefore, the specification is also enabling for the subject matter as claimed.

Dependent claims have been amended for proper antecedent basis (*e.g.*, Claims 6, 8-10, 12, 22, 65, 68-71, 94, 100-102, 105, 106 and 110) and/or to promote further clarity (*e.g.*, deleting the term "substantially homologous" from Claims 34, 55-58 and 82). Claims 95-98 are amended for clarity and specify a "moiety" instead of an "additional domain," a "linker" instead of a "linking domain" and "chemical entities" instead of "chemical moieties." Support for these amendments can be found in the specification, for example at page 7, lines 6-11 and 25-29; page 10, lines 28-29; page 12, lines 16-23; page 15, lines 7-13 and page 16, lines 4-27.

Applicants submit that the polypeptide of claim 99, even in an non-isolated form, is not directed towards non-statutory subject matter at least because the polypeptide comprising at least one peptide or protein having sialidase activity that cleaves α(2,3)-Gal and/or α(2,6)-Gal linkages; and at least one peptide or protein that binds to a glycosaminoglycan (GAG) on the surface of a target cell is not naturally occurring.

With regard to any provisional rejections that may be set forth under the judicially created doctrine of obviousness-type double-patenting (for example against co-pending Application Serial No. 10/939,262), without addressing their merit or conceding their propriety, the rejection(s) will be addressed as appropriate upon indication that there is allowable subject matter in one or more application(s) at issue.

Conclusion

In connection with the filing of a Request for Continued Examination (RCE), Applicants respectfully request consideration and entry of the amendments and remarks provided herein. Applicants submit that the pending claims are in condition for allowance, which action is respectfully requested. If it would expedite allowance of the pending claims, the Examiner is invited to telephone the undersigned at (617) 521-7041.

The fees for the petition for extension of time and RCE are being paid concurrently herewith on the Electronic Filing System (EFS) by way of deposit account authorization. Please apply any other charges or credits to deposit account 06-1050, referencing attorney docket no. 21865-0002001.

Respectfully submitted,

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